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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/037,299	10/25/2001	Stewart Thomas Leslie	208.1009	4506
23280	7590	01/26/2004	EXAMINER	
DAVIDSON, DAVIDSON & KAPPEL, LLC 485 SEVENTH AVENUE, 14TH FLOOR NEW YORK, NY 10018			YOUNG, MICAH PAUL	
			ART UNIT	PAPER NUMBER

1615

DATE MAILED: 01/26/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/037,299

Applicant(s)

LESLIE, STEWART THOMAS

Examiner

Micah-Paul Young

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 November 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-17 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-17 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

DETAILED ACTION

Notice: Due to newly presented art, the previous Notice of Allowability has been withdrawn and the following represents a rejection under said newly presented art.

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1,2,4-14, and 16 rejected under 35 U.S.C. 102(b) as being anticipated by Lee (WO 90/04965 hereafter referred to as '965). The claims are drawn to a transdermal composition comprising an opioid analgesic and distressing substance. The distressing substance is not permeable through the skin, yet will negate the opioid effects of the opioid if administered via bolus injection or oral delivery.

3. '965 discloses a transdermal preparation and device comprising an opioid analgesics and an opioid antagonists. The antagonist negates the analgesic properties of the opioid if the dosage form is delivered via bolus injection or oral delivery (abstract). The antagonist is not permeable through the skin in the transdermal presentation, and is incorporated with the same vehicle of the opioid analgesic (abstract). The transdermal device comprises an aqueous alcohol environment (example), a release liner and a backing layer (figures). The drugs listed as useful in the invention include fentanyl, buprenorphine butorphanol, cocaine and methadone (pg. 4, lin. 14 –

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20). The device can be either a reservoir or a monolithic patch (figures). These disclosures along with others render the claims anticipated.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

6. Claims 3, 15 and 17 rejected under 35 U.S.C. 103(a) as being unpatentable over the combined disclosures of Lee et al (WO 90/04965 hereafter referred to as '965) and Parnell (USPN 5,051,426 hereafter referred to as '426). The claims are drawn to a transdermal composition comprising an opioid analgesic and distressing substance. The distressing substance is not permeable through the skin, yet will negate the opioid effects of the opioid if administered via bolus injection or oral delivery. The distressing compounds are recited as ergolides.

7. As disclosed above, '965 discloses a transdermal device and formulation comprising opioid analgesics and antagonists which are impermeable through the skin, yet incorporated with

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the same vehicle. The antagonist negates the analgesic effects of the opioid in the vent of misuse. What is lacking is a disclosure of ergolide compounds as possible antagonists or distressing compounds.

8. '426 discloses methods and compositions for the treatment of drug-dependent withdrawal symptoms (abstract). The composition delivers a CNS stimulant, which can be opioid analgesics such as codeine and morphine (col. 5, lin. 30 – 40), in association with a serotonin antagonist such as an ergolide (col. 4, lin. 26 – 48). The antagonist inhibit the action of serotonin, essentially removing the euphoric properties of the composition. Ethanol can be used as a solvent for the composition (col. 6, lin. 55 – 63). The composition can be delivered in various transdermal preparations (col. 6, lin. 13 – 18). Since the serotonin antagonists of '426 are used for the same function as the antagonists of '965, it would be within the level of skill in the art to substitute the ergolide compounds into the formulation of '965.

9. With these things in mind a skilled artisan would have been motivated to combine the antagonists of '462 into the formulation of '965 in order to treat withdrawal symptoms, and remove the euphoric properties, effectively deterring misuse. It would have been within the level of skill in the art to combine the teachings and suggestions of the art with an expected result of a transdermal formulation where useful in treating withdrawal symptoms, while simultaneously deterring misuse of the dosage form by removing the euphoric or analgesic properties of the dosage form.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Micah-Paul Young whose telephone number is 703-308-7005

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(After 2/3/04 can be reached at 571-272-0608). The examiner can normally be reached on M-F 7:00-4:30 every other Monday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K Page can be reached on 703-308-2927 (After 2/3/04 can be reached at 571-272-0602). The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1234.

Micah-Paul Young
Examiner
Art Unit 1615

MP Young


THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
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